



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Registration: Myoderm

[Docket No. DEA-392]

ACTION: Notice of registration.

SUMMARY: Myoderm applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Myoderm registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION:

By notice dated January 4, 2016, and published in the **Federal Register** on January 11, 2016, 81 FR 1207, Myoderm, 48 East Main Street, Norristown, Pennsylvania 19401 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Myoderm to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the following basic classes of controlled substances:

<u>Controlled Substance</u>	<u>Schedule</u>
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form for clinical trials, research, and analytical purposes.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing, research, and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial sale.

Dated: April 29, 2016.

Louis J. Milione,
Deputy Assistant Administrator.